

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILR	NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/750,196	12/31/2003		Beat T. Weber	AM100907 C1	AM100907 C1 9169	
25291	7590	03/09/2006		EXAMINER		
WYETH PATENT LAV	N GROUP	,	BARTS, SAMUEL A			
5 GIRALDA I			ART UNIT	PAPER NUMBER		
MADISON, N	NJ 07940			1621		

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/750,196	WEBER, BEAT T.					
Office Action Summary	Examiner	Art Unit					
	Samuel A. Barts	1621					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
 Responsive to communication(s) filed on <u>14 December 2005</u>. This action is FINAL. 2b) ☐ This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. 							
Disposition of Claims							
4) ☐ Claim(s) 1 and 2 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1 and 2 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.						
Application Papers							
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 							
Priority under 35 U.S.C. § 119							
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:						

Application/Control Number: 10/750,196 Page 2

Art Unit: 1621

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed December 14, 2005 have been fully considered but they are not persuasive.

Applicant has argued that Jerussi et al do not teach the Odesmethylvenlafaxine free base (ODV) as a crystal. Applicant alleged that the Jerussi et al possibly failed to make the crystalline form of the free base of ODV because of the pH used in recovering the final product. This is not a convincing argument. Jerussi et al clearly indicated the recovery of the free base of ODV as a solid. In addition, Jerussi et al clearly taught that the compound was 99.9% pure. Jerussi et al simply did not state that the solid was a crystal. However, the solid compounds which are recovered in synthetic processes are normally crystalline in nature. In other words, the other forms of solids, such as an amorphous form, are the exception not the rule. Thus it is reasonable to assume that the 99.9% ODV compound was in crystalline form in the prior art of Jerussi et al unless otherwise indicated.

¹ See example 2 on pages 20-21.

Applicant has argued that Husbands does not teach the crystalline form of ODV. Applicant has provided evidence that indicates that the ODV recovered in Husbands was in the form of a glass. This evidence is convincing to the extent of removing Husbands as an anticipatory reference. However, Husbands still renders obvious the instant claims. One skilled in the art would be have been motivated to make the crystalline form of ODV because a skilled artisan would be motivate to purify a well-known pharmaceutical compound. The purified pharmaceutical compounds are desired in order to minimize the effects of impurities as well as to make pure pharmaceutical salts of the free base ODV.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jerussi et al (WO 00/59851).

Art Unit: 1621

See example 2 on pages 20-21. Also see previous office action and the examiner's response to applicant's arguments addressed herein.

5. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husbands (US 4,535,186).

See previous office action and the examiner's response to applicant's arguments addressed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A. Barts whose telephone number is 571-272-2870. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Samuel A Barts

Page 5

Primary Examiner Art Unit 1621

SB